



General

Guideline Title

Optimal timing of femur fracture stabilization in polytrauma patients: a practice management guideline from the Eastern Association for the Surgery of Trauma.

Bibliographic Source(s)

Gandhi RR, Overton TL, Haut ER, Lau B, Vallier HA, Rohs T, Hasenboehler E, Lee JK, Alley D, Watters J, Rogers FB, Shafi S. Optimal timing of femur fracture stabilization in polytrauma patients: a practice management guideline from the Eastern Association for the Surgery of Trauma. *J Trauma Acute Care Surg*. 2014 Nov;77(5):787-95. [51 references]

Guideline Status

This is the current release of the guideline.

EAST Practice Management Guidelines Work Group. Practice management guidelines for the optimal timing of long bone fracture stabilization. Winston-Salem (NC): Eastern Association for the Surgery of Trauma (EAST); 2000. 39 p. [25 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The strength of recommendation (strong or weak/conditional) and levels of evidence (high, moderate, low or very low) are defined at the end of the "Major Recommendations" field.

In trauma patients with open or closed femur fractures, the panel suggests early (<24 hours) open reduction and internal fracture fixation. This recommendation is conditional, and the strength of the evidence is low. Early stabilization of femur fractures shows a trend (statistically insignificant) toward lower risk of infection, mortality, and venous thromboembolism (VTE). Therefore, the panel concludes that the desirable effects of early femur fracture stabilization probably outweigh the undesirable effects in most patients. Conditional recommendation (low quality of evidence).

Definitions:

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Methodology Levels for Rating the Quality of Evidence

Quality Level	Definitions
High	Very confident that the true effect lies close to estimate of effect.

Moderate	Moderate effect; true effect is likely close to estimate of effect but may be substantially different.
Low	Limited confidence; true effect may be substantially different from estimate of effect
Very Low	Little confidence; true effect likely substantially different from estimate of effect.

GRADE Definition of Strong and Weak Recommendation

	Strong Recommendation	Weak/Conditional Recommendation
For patients	Most patients would want the recommended course of action.	Most patients would want the recommended course of action, but many would not.
For clinicians	Most patients should receive the recommended course of action.	Different choices will exist for different patients, and clinicians should help patients decide.
For policy makers	Recommended course should be adopted as policy.	Considerable debate and stakeholder involvement needed to make policy.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Femur fracture

Guideline Category

Management

Treatment

Clinical Specialty

Critical Care

Emergency Medicine

Orthopedic Surgery

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate the comparative effectiveness of early (<24 hours) versus late (>24 hours) open reduction and internal fixation of an open or closed femur fracture in trauma patients, particularly in preventing mortality, infection, nonunion/malunion, amputation, and venous thromboembolism (VTE)

Target Population

Trauma patients with an open or closed femur fracture

Interventions and Practices Considered

1. Open reduction and internal fixation within 24 hours of injury
2. Open reduction and internal fixation greater than 24 hours after injury (not recommended)

Major Outcomes Considered

- Mortality
- Infection
- Nonunion/malunion
- Amputation
- Venous thromboembolism (VTE)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Inclusion Criteria for This Review

Study Types

For the purpose of making recommendations, studies included randomized controlled trials (RCTs), prospective observational or retrospective studies, and case-control studies. Only studies pertaining to open reduction and internal fixation of open or closed femur fractures were included.

Participant Types

The panel included studies with adult patients, any sex, and with no restriction on inclusion of ethnicities or patients with comorbidities. Meta-analyses, case reports, letters, and reviews containing no original data or comments were excluded.

Intervention Type

The panel included studies comparing open reduction and internal fixation performed within 24 hours from the time of injury to stabilization performed greater than 24 hours after injury.

Outcome Measure Types

An initial list of all relevant outcomes (infection, nonunion/ malunion, compartment syndrome, venous thromboembolism (VTE), fat embolism syndrome, regional pain, neurologic impairment, arthritis, hardware failure, impaired function, mortality, or amputation) was generated and distributed to panelists. Eight panelists independently rated the relative importance of each outcome on a 9-point scale ranging from 1 (less important) to 9 (critically important for decision making). The five highest rated outcomes were selected as follows: mortality, infection, VTE, nonunion/malunion, and amputation. A systematic review of the literature was then conducted to identify relevant articles. Each article was evaluated independently by three members of the committee to extract pertinent data. The panel did not find any articles with data regarding the outcomes of nonunion/malunion and amputation, so these outcomes were excluded from the analysis.

Other outcomes considered were respiratory complications of fixation such as adult respiratory distress syndrome, fat embolism, pneumonia, and other pulmonary dysfunction. However, these outcomes were not included in this review.

Review Methods

Search Strategy

The literature search and appraisal were based on guidelines for systematic reviews. A MEDLINE and Cochrane search was conducted to identify English language human subjects prospective RCTs, non-RCTs, existing systematic reviews, guidelines, case-control, and observational studies published before November 2013. Search terms included (1) *femoral fractures*, (2) *long bone stabilization*, (3) *timing fixation*, (4) *delayed fixation*, (5) *early fixation*, (6) *immediate fixation*, (7) *fracture fixation*, (8) *timing fracture*, and (9) *timing osteosynthesis*, alone or in combination. In addition to the electronic search, the bibliographies of relevant articles and systematic reviews were hand searched to find additional potentially appropriate publications to be included in this review.

Study Selection

A single panelist conducted the literature search and assessed the titles and abstracts to identify relevant publications, applying inclusion criteria. Case reports and review articles were excluded. The resulting studies then underwent full-text review by three independent reviewers to determine appropriateness for inclusion.

Results

The panel retrieved 9,091 articles during the first phase of the literature search, of which 9,032 were excluded by duplicate removal and title review (see Figure 1 in the original guideline document). Fifty-nine articles addressing optimal timing of long bone fracture stabilization underwent a full review to identify 11 studies comparing early (<24 hours) versus late (>24 hours) open reduction and internal fixation of femur fractures in trauma patients.

Number of Source Documents

Of the 11 studies identified, 1 was a prospective randomized study and 10 were retrospective cohort studies.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Methodology Levels for Rating the Quality of Evidence

Quality Level	Definitions
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Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction and Management

Data were extracted by a single reviewer, confirmed by two other reviewers, and entered into Review Manager X.6 (RevMan). Information included authorship, publication year, methodology of the study, population, intervention, and relevant outcome measures.

Methodological Quality Assessment

The articles were evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. The quality of evidence was classified as high, moderate, low, or insufficient for each outcome (see the "Rating Scheme for the Strength of the Evidence" field). The quality of evidence is reflected as the extent to which one can be confident that an estimate of effect is correct and includes an explicit consideration of the following domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias.

Measures of Treatment Effect

The panel created a detailed set of evidence tables containing all abstracted information. Clinical outcomes, including mortality, infection, and venous thromboembolism (VTE) reported in each included study, were individually pooled for meta-analysis. The relative risk (RR) and 95% confidence interval (CI) were calculated for each study using a random-effects model. A $p < 0.05$ was considered significant for all analyses. STATA 12.1 (College Station, TX) statistical analysis software was used for all statistical analyses. There were not enough data to undertake meta-analysis for the other two outcomes (nonunion/malunion and amputations).

Assessment of Heterogeneity

Potential heterogeneity existed because of population differences, different types of surgery, and how patients were defined. The panel examined these differences across studies to assess clinical and methodological heterogeneity. For the meta-analysis, they used RevMan to calculate the I² statistic to determine the proportion of variation between studies attributable to heterogeneity, and variation was categorized as "low" (I²=25%-49%), "moderate" (I²=50%-74%), or "high" (I²=74%-100%).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Recommendations were developed based on the results of the meta-analysis as well as the quality of evidence, and per the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach, they were classified as either "strong" or "weak" (see the "Rating Scheme for the Strength of the Recommendations" field).

These recommendations were based on the quality of evidence and the risk-versus-benefit ratio.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations Assessment Development, and Evaluation (GRADE) – Definition of Strong and Weak Recommendation

	Strong Recommendation	Weak/Conditional Recommendation
For patients	Most patients would want the recommended course of action.	Most patients would want the recommended course of action, but many would not.

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Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

All authors participated in the critical review of the original guideline document.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Proponents of early stabilization point to more desirable outcomes, such as fewer complications, shorter hospital stays, and lower costs of care

Potential Harms

Opponents suggest that early definitive stabilization may not be safe for the most severely injured patients or those with associated head, chest, or serious abdominal injuries due to increased blood loss, surgical stress, and pulmonary complications and that these and other factors may lead to increased mortality. Several other researchers have suggested a lack of benefit to early stabilization.

Qualifying Statements

Qualifying Statements

- The Eastern Association for the Surgery of Trauma (EAST) is a multi-disciplinary professional society committed to improving the care of injured patients. The Ad hoc Committee for Practice Management Guideline Development of EAST develops and disseminates evidence-based information to increase the scientific knowledge needed to enhance patient and clinical decision-making, improve health care quality, and promote efficiency in the organization of public and private systems of health care delivery. Unless specifically stated otherwise, the opinions expressed and statements made in this publication reflect the authors' personal observations and do not imply endorsement by nor official policy of EAST.
- "Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care

for specific clinical circumstances."⁶ These guidelines are not fixed protocols that must be followed, but are intended for health care professionals and providers to consider. While they identify and describe generally recommended courses of intervention, they are not presented as a substitute for the advice of a physician or other knowledgeable health care professional or provider. Individual patients may require different treatments from those specified in a given guideline. Guidelines are not entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results. While guidelines can be written that take into account variations in clinical settings, resources, or common patient characteristics, they cannot address the unique needs of each patient nor the combination of resources available to a particular community or health care professional or provider. Deviations from clinical practice guidelines may be justified by individual circumstances. Thus, guidelines must be applied based on individual patient needs using professional judgment.

- This guideline represents a very detailed summary of the literature regarding open reduction and internal fixation of femur fractures and surgical timing and is meant to inform the decision-making process, not replace clinical judgment. The optimal timing for internal fixation remains controversial.

* Institute of Medicine. Clinical practice guidelines: directions for a new program. MJ Field and KN Lohr (eds) Washington, DC: National Academy Press. 1990: pg 39.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2000 (revised 2014 Nov)

Guideline Developer(s)

Eastern Association for the Surgery of Trauma - Professional Association

Source(s) of Funding

Eastern Association for the Surgery of Trauma (EAST)

Guideline Committee

Eastern Association for the Surgery of Trauma (EAST) Practice Management Guidelines Committee

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

E.R.H. is the primary investigator and supported by a contract (CE-12- 11-4489) from the Patient-Centered Outcomes Research Institute (PCORI) entitled "Preventing Venous Thromboembolism: Empowering Patients and Enabling Patient-Centered Care Via Health Information Technology." E.R.H. receives royalties from Lippincott, Williams, & Wilkins for a book, "Avoiding Common ICU Errors," and has given expert witness testimony in various medical malpractice cases. E.R.H. is a member of the EAST Board of Directors and Chairs the EAST Guidelines Committee. R.R.J. is a speaker for Lifecell. E.H. is supported by grants from Synthes and Smith and Nephew and is a consultant for Synthes. E.H. is also a speaker for AO North America Faculty. B.L. is the co-principal investigator of a contract (CE-12-11-4489) with PCORI entitled "Preventing Venous Thromboembolism: Empowering Patients and Enabling Patient-Centered Care Via Health Information Technology." H.A.V. is a member of the board for the Orthopaedic Trauma Association and Center for Orthopaedic Trauma Advancement. H.A.V. receives support for the METRC research consortium funded by the Department of Defense, the FAITH research study funded by the National Institute of Health, and the sacrum research study funded by the Orthopaedic Trauma Association. J.W. is supported by a grant to study acupuncture in the intensive care unit (ICU) by the Medical Research Foundation and receives travel expenses for PROPPR trial meetings. S.S., F.B.R., T.R., D.A., J.K.L., and T.L.O. have nothing to disclose.

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Guideline Availability

Electronic copies: Available from the [Eastern Association for the Surgery of Trauma \(EAST\) Web site](#) .

Print copies: Available from the Eastern Association for the Surgery of Trauma Guidelines, c/o Tiffany L. Overton, MPH, JPS Health Network, Trauma Services, 1500 S Main St, Fort Worth, TX; email: toverton@jpshealth.org.

Availability of Companion Documents

The following is available:

- Kerwin AJ, Haut ER, Burns JB, Como JJ, Haider A, Stassen N, Dahm P, Eastern Association for the Surgery of Trauma Practice Management Guidelines Ad Hoc Committee. The Eastern Association of the Surgery of Trauma approach to practice management guideline development using Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology. J Trauma Acute Care Surg. 2012 Nov;73(5 Suppl 4):S283-7. Electronic copies: Available from the [Eastern Association for the Surgery of Trauma \(EAST\) Web site](#) .

Patient Resources

None available

NGC Status

This summary was completed by ECRI on September 17, 2001. The information was verified by the guideline developer on September 27, 2001. This summary was updated by ECRI Institute on February 13, 2015.

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